

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Services

Animal Care

920 Main Campus Drive Suite 200 Raleigh, NC 27606

Tel No. 919-855-7100 Fax No. 919-855-7123 February 2, 2007
CERTIFIED MAIL
RETURN RECEIPT
7001 0360 0000 2162 6125
RE: Cust. # 223
Lic/Reg # 31-R-0017
Warning Notice
APHIS Form 7060

Cleveland Clinic Foundation Research Institute Bio Research Unit / NC50 9500 Euclid Ave Cleveland, OH 44195

Dear (b)(6), (b)(7)c

The enclosed APHIS Form 7060, "Official Warning, Violation of Federal Regulations," is being issued to you for alleged violations of the Federal Animal Welfare Act. This notice is being issued at this time as a serious warning that if you fail to comply with the requirements of the Animal Welfare Act in the future, this citation and all past and future documented violations will be used to justify a more severe penalty. The Animal Welfare Act provides for penalties of up to \$3,750 per violation. If you have any questions regarding this citation or the Animal Welfare Act, please contact this office at the above address or phone (919) 855-7100.

Sincerely,

Elizabeth Goldentyer, DVM Eastern Regional Director

Animal Care

Enclosure

cc: R. Huttenlocker, IES

N. Harlan, DVM

E. Magid, SACS

K. Carter-Corker, ARD OH (223) 31-R-0017

nimal are

Animal Care is a part of the Department of Agriculture's Animal and Plant Health Inspection Service.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

OFFICIAL WARNING



VIOLATION OF FEDERAL REGULATIONS

CASE NO. **OH07014**

VIOLATOR

Customer # 223 Certificate # 31-R-0017 Cleveland Clinic Foundation Research Institute

ADDRESS (Street, City, State, Zip Code)

Bio Research Unit / NC 50 9500 Euclid Ave Cleveland, OH 44915

The Department of Agriculture has evidence that on or about **January 24, 2007**, you or your organization committed the following violation of Federal Regulations:

9 CFR, SECTION

Failure to

2.31 (d)(1)

• Have IACUC review activities involving animals. In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements.

(There was a procedure conducted on a dog that was not done under an approved protocol. The procedure was done for the training of corporate sales people. The physician ordering the animal utilized an approved research protocol with no training component to request the animal be delivered to the lab. This animal had been purchased from a licensed dealer and had the initial preparatory surgery for the originally intended research protocol. The Doctor diverted the animal to his use for the training program he was conducting.)

9 CFR, SECTION

Failure to

2.33 (b)(1)

Establish and maintain programs of adequate veterinary care that include the availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter

(The surgical area where this procedure took place is extremely cluttered with one very large wood packing crate, a wooden pallet and several cardboard boxes. These are all untreated and not readily cleanable in any way. This does not permit adequate cleaning to allow for sterile technique. There is also a large accumulation of outdated wrapped implements hanging on the wall and stored on the floor in boxes. This increases the clutter and difficulty in cleaning.)

Titles 7 & 9 Code of Federal Regulations were promulgated to help prevent the spread of animal and plant pests and diseases and assure the humane treatment of animals. Since violations of the regulations can have serious and costly impact detrimental to the public interest, you are warned of this violation. Any further violation of these regulations may result in the assessment of a civil penalty or criminal prosecution. If you have any questions concerning this warning or violation, please contact the listed APHIS Official.

APHIS OFFICIAL (Name and Title)		OFFICE ADDRESS:
Elizabeth Goldentyer, DVM	Regional Director	920 Main Campus Dr., Suite 200
SIGNATURE	DATE ISSUED	Raleigh, NC 27606
Elin Ce-e-	212107	TELEPHONE NO. AC (919) 855-7100
FOR PERSONAL SERVICE - RECEIVE	D BY: (Name and signature)	DATE RECEIVED:
FOR CERTIFIED MAIL - RECEIPT NO:		

7001 0360 0000 2162 6125

APHIS FORM 7060

Previous editions may be used

(JUN 91) PART 1 - VIOLATOR

Cleveland Clinic

January 11, 2007



Dr. Ellen Magid USDA, Animal Care 920 Main Campus Drive, Suite 200 Raleigh, NC 27606

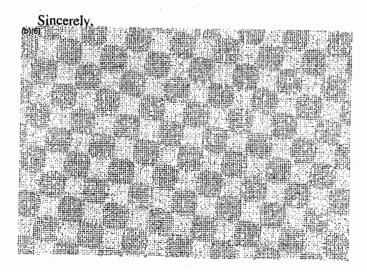
Dear Dr. Magid:

This letter is to inform you of a noncompliance that occurred yesterday at the Cleveland Clinic Lerner Research Institute (A3047-01, USDA #31-R-0017).

The noncompliance involved an approved protocol using a canine model of cerebral aneurysm. The incident involved one dog. A procedure was performed (intracarotid injection of coils for the purpose of embolization of the experimental aneurysm). Although the creation of the aneurysm model was approved by the IACUC in this protocol, this specific experimental procedure involving injection of coils was not approved. In addition, this procedure was done in a workshop format involving physician training of sales personnel for the commercial sponsor producing the coils. Our IACUC has a policy that workshops involving animals are not approved if it is for the exclusive purpose of training sales personnel. We do approve workshops for physician training for new devices.

The IACUC became aware of this incident when the IACUC Office received a fax that was sent by PETA to the coil manufacturer. A copy of the fax is enclosed. We have been informed by the Media Relations unit at the Cleveland Clinic that PETA has also communicated with The Cleveland Plain Dealer newspaper, and that an article will be published in the January 12 morning edition.

Our institution is committed to take appropriate action concerning the investigators involved in this incident. The CEO, the Chief-of-Staff and the Office of the General Counsel have all played an active role in assessing this situation over the last 24 hours. I will send you a follow-up letter informing you of the corrective actions that will be taken.



The Cleveland Clinic Foundation Lerner Research Institute

Cleveland Clinic

January 19, 2007



Dr. Ellen Magid USDA, Animal Care 920 Main Campus Drive, Suite 200 Raleigh, NC 27606

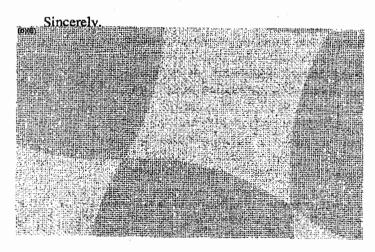
Dear Dr. Magid:

This is a follow-up to the letter that I sent to you on January 11, 2007 concerning a protocol noncompliance that occurred on January 10, 2007 at the Cleveland Clinic Lerner Research Institute (A3047-01, USDA # 31-R-0017).

The IACUC convened a meeting to discuss the noncompliance on January 18, 2007. A quorum of the IACUC was present. After lengthy discussion, the IACUC unanimously recommended to me in my capacity as the Institutional Official, the following corrective measures:

- 1. The investigator directly responsible for the noncompliance will not be allowed to perform research involving animals for a period of two years starting from the date of the noncompliance.
- 2. All investigators involved in endovascular research will be required to complete a rigorous retraining program before they will be allowed to perform animal research.
- The endovascular research group will be required to develop a formal internal set of guidelines involving animal research. This will include internal checks and balances designed to prevent a future noncompliance.

In addition to these corrective actions recommended by the IACUC, the Institution has delineated additional corrective measures to reflect the seriousness by which the Institution has viewed this noncompliance. I would be happy to provide any additional information that you might require regarding this issue.





Animal and Plant Health inspection Service



P.82/82 223 cust_id 324000 insp_ld 6121 site_id

CLEVELAND CLINIC FOUNDATION RESEARCH INSTITUTE

BIO RESRC UNITINOSO, 9500 EUCLID AVE CLEVELAND, OH 44195 Customar ID: 223

Contificato: 31-R-0017

Site: 001 .

CLEVELAND CLINIC

Inspection

Typo: ROUTINE INSPECTION

Date: JAN-24-2007

2.31 (d X 1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in engoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however. That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in engoing activities meet the following requirements

There was a procedure conducted on a dog that was not done under an approved protocol. The procedure was done for the training of corporate sales people. The physician ordering the animal utilized an approved research protocol with no training component to request the animal be delivered to the lab. This animal had been purchased from a licensed dealer and had the initial preparatory surgery for the originally intended research protocol. The Doctor diverted the animal to his use for the training program he was conducting. This is a violation of the regulations requiring that all animal usage be conducted under approved protocols following the delineated guidelines set down for research and mandated by law. These guidelines are designed to prevent animal wastage and to protect the animals from unnecessary pain and distress.

The research facility has conducted a therough investigation and provided an adequate response in both disciplinary actions for this individual and additional training and checks and balances to attempt to prevent any future incidences of this nature. Corrected

2.33 (4)(1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter

wooden paliet and several cardboard boxes. These are all untroated and not readily cleanable in any way. This does not permit adequate cleaning to allow for sterile technique. There is also a large accumulation of outdated wrapped implements hanging on the wait and stored on the floor in boxes: This increases the clutter and difficulty in cleaning. This does not provide for adequate vaterinary care for the animals utilized in this room.

Correct by: next use for animal research

Propered By-> ?- > Hand DVM	
NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care	Date:
Received By:	JAN-25-2007
	Date;
	JAN-26-2007
Page 1 of	



United States Department of Agriculture Animal and Plant Health Inspection Service

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NHARLAN

CLEVELAND CLINIC FOUNDATION RESEARCH INSTITUTE

BIO RESRC UNIT/NC50, 9500 EUCLID AVE CLEVELAND, OH 44195 Customer ID: 223 Certificate: 31-R-0017

Site: 001

CLEVELAND CLINIC

inspection

Type: ROUTINE INSPECTION

Date: MAY-31-2008

2.31 (d X 1 X II)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(ii) The principal investigator has considered alternatives to procedures that may cause more then momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

The section in the protocols for determining whether there were any alternatives to painful procedures did not adequately address the point in the following protocols: pigs - ARC#s 00766, 07493, dog - Arc #s 07349, 07627, 07438, 07906, primate - Arc#s 007481, 07748, Rabbit - Arc# 07739.

On all of these protocols only one search engine was used to search for alternatives to Painful Procedures. To conduct an adequate search and be sure that all reasonable possibilities are covered at least two different search engines should be used. They should be selected based on the topic to be researched. If a literature search is not available than an appropriate alternative must be used and documented.

This must be properly done to assure that all possible care is being taken to provide for the animals health and well being. All protocols must be checked, not just the ones that I have identified in this write up.

Note: the more recent protocols now use two search engines in their search strategy, it is just the older protocols that have this problem.

Correct by: 7/1/06

3.11 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin. Premises must be kept free of accumulations of trash, Junk, waste products, and discarded matter. Weeds, grasses, and bushes must be controlled so as to facilitate cleaning of the premises and pest control, and to protect the health and well-being of the animals.

Clutter in the surgical rooms and hallway. There was an excessive buildup of clutter in the hallways in the main operating room areas. This needs removed to permit adequate husbandry and prevent potential problems with pests. This is for the health and well being of the animals.

Correct by: 6/21/06

There was a pile of clutter on the floor in one surgery room during a non survival procedure on a pig. There was a table that could have been used to hold these supplies in one corner that was complately empty. These items need to be off the floor

Prepared By: NORMA JEAN HARLAN, D V M , USDA, APHIS, Animel Care	Date:
Title: (CTEDINADY ASEDICAL OFFICE) (Spector ID: 1004	MAY-31-2006
Received By:	Date: MAY-31-2008



United States Department of Agriculture Animal and Plant Health Inspection Servic.



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JUN (7 200644878 insp_id 6121 site_ld

for surgical purposes. Non survival procedures for major species must be done in a clean if not sterile manner. Correct by: 6/6/06

Left a copy of Policy 12, Consideration of Alternatives to Painful/ Distressful Procedures

Prepared By:

NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care

Title: ve

ETEDINADY MEDICAL OFFICER ...

pector ID: 1004

Date:

MAY-31-2006

Received By: Title:

Date:

MAY-31-2006



United States Department of Agriculture Animal and Plant Health Inspection Servi

FEB 08 2006

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CLEVELAND CLINIC FOUNDATION RESEARCH INSTITUTE

BIO RESRC UNIT/NC50, 9500 EUCLID AVE CLEVELAND, OH 44195 Customer ID: 223 Certificate: 31-R-0017

Site: 003

NORTHEAST OHIO UNIVERSITY

Inspection

Type: ROUTINE INSPECTION

Date: JAN-31-2006

No animals present during this inspection. No noncompliant items identified during this inspection.

Prepared By:

NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care

Titie:

ORMA JEAN MARCAN, D. V.M., USDA, APRIS, AMINAI CAIR

Received By:

Title

Date:

JAN-31-2006

Date:

JAN-31-2006



United States Department of Agriculture Animal and Plant Health Inspection Service

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INSPECTION REPORT

CLEVELAND CLINIC FOUNDATION RESEARCH INSTITUTE

BILOGICAL RESOURCES UNIT/NC50 9500 EUCLID AVE CLEVELAND, OH 44195 Customer ID: 223 Certificate: 31-R-0017

Site: 001

CLEVELAND CLINIC

Inspection

Type: ROUTINE INSPECTION

Date: JUN-20-2005

2.31 (d)

REPEAT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually

In 2003, 2004, and now 2005 the Cleveland Clinic IACUC reported errors in the annual review of their animal use protocols. This time it was protocol that should have been reviewed the end of August, 2004. This oversight was not noted until May, 2005. The necessary review information was not received until 5/16/05. The researcher claimed at the time that it was a duplicate of information sent prior to the end of August, 2004. There was one difficulty with the accuracy of that observation. The animals listed on the report were not received until mid September. The report itself was signed 5/16/05. Continuing ongoing reviews must be conducted at least annually of all animal activity. This is to maintain adequate control of ongoing research activities by the IACUC, to prevent animal harm, loss, or wastage.

Note, the following corrections are being implemented to prevent any reoccurences of this incident:

- 1) A 90, 60, and 30 day reminder is being sent to each researcher in advance of the annual renewal information being required.
- 2) The first day of the month following the due date for their renewal the researcher is notified that no further activity is to occur until such time as they have contacted the IACUC and corrected this problem. When this notice goes up, salmon colored animal ID cards are placed on the animals, identifying them as belonging to the facility protocol. The caretakers will be monitoring for any unauthorized activity.
- 3) Taking too long to rectify the situation could result in the requirement to rewrite the entire protocol and pursue full IACUC approval.

One last item to be implemented is to check for the status of the protocol prior to the arrival of the animals. It is presently being checked at the time of ordering, but some orders take long enough that this status changes in between.

Prepared By:	NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care	Date:
Title:	- METERNARY MEDIAN-ARGIDED IN THE TRACE	
	(b)(7)c	JUN-20-2005
Received By:	THE REAL PROPERTY AND A CONTROL OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE	
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		Date:
Title:	A STATE OF THE STA	JUN-20-2005
	SUBJECT OF THE WALL BETTER THE TOTAL OF THE	3014-20-2005

See reverse side for additional information. Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATI

CUSTOMER NO. 223

FORM APPROVED

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

 HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

CLEVELAND CLINIC FOUNDATION BIO RESRC UNIT/NC50, 9500 EUCLID AVE CLEVELAND, OH 44195

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

REPORT OF ANIMALS USED BY	OR UNDER CONTROL O	F RESEARCH FACILITY	' (Attach additional sheets if neces	serv or use APHIS FORM 7023A J	
A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, leating, experiments, research, or surgery but not yet used for such purposes.	C. Number of enimals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- reliteving drugs.	D. Number of animals upon which experiments, teaching, research, surgary, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgeeic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anasihetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An experiments surgery, or tests. (An experiments and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	7		360		360
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			189		189
9. Non-Human Primates	9	2	6		8
10. Sheep	1		11		11
11. Pigs			209		209
12. Other Farm Animais				No.	
calves			14		14
13. Other Animals					
-					
ASSURANCE STATEMENTS					

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, teating, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is effected to this samual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarien for this rasearch fecility has appropriete authority to ensure the provision of adequate veterinary care and to oversee the sdequacy of other aspects of animal care and use.

(Chief Executive (Y HEADQUARTERS RESEARCH FACILITY OFFICIAL Officer or Legally Responsible Institutional official) cove is true, correct, and complete (7 U.S.C. Section 2143)	
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/13/2006

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS



LERNER RESEARCH INSTITUTE



November 30, 2006

United States Department of Agriculture 920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213 Registration No. 31-R-0017/223

The Cleveland Clinic submitted the FY2006 APHIS FORM 7023 and 7023A electronically on November 30, 2006. We would like to add one exception to the housing standards of the Animal Welfare Act that was reviewed and approved by the IACUC.

Animal Husbandry

Calves with implanted cardiac medical devices are maintained in pens smaller than the standards listed in the Guide for the Care and Use of Laboratory Animals.

Thank you very much,



Soe reverse eld additional informació Imetagancy Report Control No 6180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO 11-R-0017 Datower MC 293 FORM APPROVED OMERIC, 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

READQUARTERS RESEARCH FACILITY (Nome and Address, so regulered with USDA, include 2th Code)

CLEVELAND CLINIC FOUNDATION

CLEVELAND CLINIC FOUNDATION BIO RESPO: UNITINGSO, 9800 EUCLID AVE CLEVELAND, OH 44195

2. REPORTING FACILITY (List all locations where animals were housed or used in actual research, legging, teaching, or departmentation, or held for these pulposes. Actual administration of departmentation, or held for these pulposes. Actual administration of departmentation, or held for these pulposes. Actual administration of departmentation or held for these pulposes. Actual administration of departmentation or held for these pulposes. Actual administration of departmentation or held for these pulposes. Actual administration of departmentation or held for these pulposes.

CLEVELAND CLINIC CLEVELAND, OH 44196 FAGRITY LOCATIONS (MR.)
DALWOOD FARMS
WAXEMAN, OH 44869

COLLEGE OF MEDICINE ROOTSTOWN, OH 44195 RAVENS GLENN FARM PULASKI, PA 16143

A. Anipela Covered By The Animal Welfers Regulations	u. Number of shirets being bran; uandstened, or hald for use in teaching, beiling, experiments, research, or surgery but not yet used for such purposed.	C. Number of writes to post which to post in a control, esperiments, or less were conducted involving no pain, discusse, or una of path-releving divisio.	b. Number of aranda upon which experiments, teaching, respect, teaching, respect, teaching, respect, teaching, respect, teaching, respect, teaching pain or constituted involving pain or claimes to the animals and for which appropriets are freshold, analysis. Of traspolitating drugs were used.	E. Number of animate upon which teaching, experiments, research, suppay or uses were conducted involving abtompenying path or disbraid to the animals and for which the use of expropri pits a nestinal canalysis, or language source draws oversely stituted the procedures, neuros, or histoprospice of the positing, research, superiments, surgery, or looks. (An explanation of the procedures producing pain or distress in these animals and the regions such drugs were not used must be attached to this report).	F. TOTAL NO. DF ANIMAL (Cols. G + E)
4. Dogs	13		340		340
5. Cets				· <u> </u>	
6. Guines Pigs					
7. Hamsters					
6. Robbis	3		361		381
9. Non-Human Primates	4	. 9	12		21
10. Sheep	1	1	12		13
11. Pige	5		114		114
12. Other Farm Animals			·		
calves	1		32		32
13. Other Animals					
		-			

1) Profossionally acceptable standards governing the core, treatment, and use of antique, including appropriate use of anesthetic, analyses, analyses, analyses, and transplaint drugs, prior is, during, and followed by this research iscille.

2) Rean principal investigator has comidered alternatives to patrici procedures.

3) This facility is adhering to the elanderite and regulations under the Act, and it has required that expendions to the paragraps of all the exceptions by appointed by the principal investigators and expressed by the implicational Arimat Cure and Use Compressed (IACUC), A suggraps of all the exceptions to exceptions to exceptions to exceptions to exceptions. In addition to identifying the IACUC-approved exceptions. Into Extending Includes a later explanation of the exceptions. As well as the species are number of artists effected.

4) The attenting vetatination for this research healthy has appropriate sufficiently is ensure the provision of adequate vetationary care and to oversee the adequate of other suspects of artiful dept and use.

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CENTERVING BY DESCRIPTION	FIRES REDENIALL MAINTIL ALLIANA
Ichief Cassallan Adlana en 1 se	العلمكات احجم البطاعمط عاطاهم وسيرا وياتم
Cural Executive Culculation of Tele	paily Responsible Institutional official)
f	

(certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME 4 TITLE OF C.E.D. OR INSTITUTIONAL OFFICIAL (Type or Print)

.

DATE SIGNED

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 15-23 (Oct 84), which is absolute

PART 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH REPECTION SERVICE

ESISTINATION NO. 31-R-0017

CLUSTOMER NO. 223

žon.

FORM APPROVED ONG NO. 0578-0035

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

HEADQUARTERS RESEARCH FACILITY Glame and Address, as registered with USDA, include 2th Code)

CLEVELAND CLINIC FOUNDATION BIOLOGICAL RESOURCES UNIT/FF6-04 9500 BUCLID AVE CLEVELAND, OH 4416

3. REPONTING FACILITY (List all localism where arimate were housed or used in social research, tourns, leaching, or experimentation, or held for frees surposes. Attach additional Sheets if necessary.)

FACILITY LOCATIONS (#105)

COLLEGE OF MEDICINE ROOTSTOWN, OH 44185

CLEVELAND CLINIC FOUNDATION

PULASKI, PA 16143

DALWOOD FARMS WAKEMAN, OH 44888

REPORT OF ANIMALS USED BY A.	B. Hunter of				Ŧ.
Animais Covered By The Animai Western Regulations	e. Human being bred. Acadiformed, or finish for Lean to terracing, casturg, cityperinarias, research, or surgery but ner yet Lean for puch purporces.	C. Nember of minute upon which leasting, temperinalis, at look ware conducted two long no poly of pain- cellering druge,	Number of grittels upon which separingsis. Secting, readers. Surjery, or reals white conducted involving pain of allowing pain of the which, specially in temperated, analysis, or instiguibility drugs were upon.	B. Planther of entimate upon which leaching, experiments, conservative upon which leaching, experiments or delicate accordanced involving superpending paint or distross for the animals and the which the use of experiments animals are according to the use of experiments and the according to the production, experiments, angular or interpretation of the jeaching, research, experiments, angular, or tests. (An explanation of the placedures producing path of otherwise is these surious and the aspecting path chops were not used must be attached to this report.)	TOTAL NO. OF AMBAGE (Code. C = D = E)
4. Doge	R.		355		356
5. Cate					
6. Guinea Pigs					
7. Hernstera					
B. Rindolfs		24	29G		310
9. Non-Human Primates	8		7		7
10. Sheep			27		27
11, Piga	2		180		160
12. Other Farm Animate					
goets			6		
13, Cither Animala					····

- Professionally acceptable standards governing the core, treatwest, and task of entires, including appropriate use of enceptable, prefered, and transcrib, teaching, leading, surjety, or experimentation were followed by this research facility.
- 2) Each principal investigator has complemed allomatives to painful procedures.
- 3) This facility is utharing to the standards and regulations under the Act, and it has required that acceptant to the standards and regulations be specified and explained by the principal investigator and approved by the traductoral Active Committee (MCUC), a yearney of all the exceptions is attached to this among report. In Addition to identifying the IACUC-approved exceptions, this summary includes a bris explainable of the acceptant, at well at the opening and number of entrains addition.
- 4) The attanding votationalist for this research facility has appropriate authority to ground the provision of adequate valuations care and to oversee the adequacy of other aspects of animal data and use.

CERTIFICATION B	Y HEADQUARTERS RESEARCH FACILITY OFFICIAL	
(Chief Executive	Officer or Lagally Responsible Institutional official)	
I conify that the a	bove is true, correct, and complete (7 U.S.C. Section 2149)	
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME A TITLE OF C.E.O. OR RESTITUTIONAL OFFICIAL (Type of Print)	DATE SIGNED
		11/30/2004
	1	

APHIB FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (Oct 48), which is obschib

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Fallure to report sic; — to the regulations can neutral in an order to page and desist and to be subject to perall! — provided for in Section 21:0 E C	0 2 2003 See approve form for	Interagency Report Control No.
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CHRTIFICATE NUMBER: 31-R-0017 CUSTOMER HUMBER: 223	FORM APPROVED OMB NO. 0579-0036
ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	Cleveland Clinic Foundation Research Institute Biological Resources Unit何条項4 NC 9500 Euclid Ave Cleveland, OH 44195	50

S. REPORTING FACILITY (List all locations where arimals were housed or used in actual research, testing, or experimentation, or had for mose proposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (thee) - See Alwined Linking

A. Animair Covered By The Animai Walters Risguistions	El. Phyriber of grants being break, cardiformed, or held for use in tending, tenting, affections, conserved, or eurgery but not ye used for such purposes.	C. Number of sentime upon which against. respective. respectively.	D. Humber of energie upon which appariments, importing, trained rob, augmenting, of feath aways constanted involving security-ship person or districts to the entiring in miles which appropriate arrectability, amplipment, or hydratical careful availability shape word taxes.	E. Number of enimply upon which hyesting, experiments, research, surgery or testaments conducted invelving assembly path or distingue to the enimple surface with the use of appropriate enumbers, seelgade, or investigating results town adversely effected the procedures, results, or therpresented the lauching, results as the procedures, procedures procedures point of sections in these primaries at the procedures proceding point or distributed the procedures broadering point or distributed in these primaries at the response such diagraments not used must be alteredad light report 1.	F. TOTAL RUMBE: OF ANHALS (COLLIMNS C+D+E)
4. Pogs	16		409		409
s, Cata					0
8. Guinea Piga					0
7. Hamsters			40		40
6. Rathka		. 24	134		158
9, Non-human Primates	4	4	5		9
O. Sheep	2		37		37
1. Piga	1	,	176		176
2. Other Ferm Animals					
Goats			10		10
d, Other Animala					
Calves	1		28		28

ASSURANCE STATEMENTS

- 1) Professionally sometimes abundance governing the care, treatment, and use of animals, including appropriate use of anestella, ensignals, and emergining shape, prior to, during, and following estuad rese lanceting, senting. Senting, are dependent animals were followed by this researce, teeting.
- 2) Each principal investigator has considered alternatives to point a procedure.
- 3) This facility is administrate and requisitions under the Am, and it has required that complians as the Helicitatic and regulations by a specified and asplained by the principal pressignar and ap invitational Animal Care and Use Committee (IACUC). A summary of all much examples to absolute by the animal report. In addition to identifying the IACUC-approved exemploses, this summary in biful expectation of the exceptions, as well as the species and mainter of arbitrate effected.
- 4) The spending velocitation for this research locally has appropriate authority in treasure the provision of admittable relativity care and to oversee the admittable district expects of entrail care and care.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer of Legisly Responsible Intelligional Official)		
SCHATUF	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL. (Type of Print)	DATE SIGNED
APHIS FORM 7029 (Replaces VS FORM 18-22 (OCT 86), which is obsolute.)		<u> المثالث المث</u>



To: Lesia.M.Banks@aphis.usda.gov

cc: Subject: # of dogs used in medical research

Lesia,

These numbers include all the dogs reported as having been used in research in any way.

'04 - 65,012

'05 ~ 66,610

'06 - 49,898

Call me if you need anything else. Betty